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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/549,488 | 07/31/2006 | Daniel E Katzman | NEU-102.1P US | 9463 |

7590 03/13/2008

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| EXAMINER | |
|---|---|
| PATTON, AMANDA K | |
| ART UNIT | PAPER NUMBER |
| 3762 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 03/13/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/549,488 | KATZMAN ET AL. | |
| | Examiner | Art Unit | |
| | Amanda Patton | 3762 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *07 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3-16 and 20-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-16, and 20-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Amendment*

Applicant's amendment dated January 7, 2008 has been considered. In response to the amendment of claim 3, the rejection under 35 USC 112, second paragraph has been withdrawn. Currently claims 1, 3-16, and 20-25 are pending in this application.

### *Specification*

The disclosure is objected to because of the following informalities:

- Page 13, line 23 refers to an international application but does not contain the correct application number. The correct PCT number is believed to be PCT/US2004/008056, published as WO 2004/082624.
- Claim 6 does not end in appropriate punctuation.
- Claim 16 does not have a space between the word "Claim" and the word "15".

Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 7-8, and 20-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Bacon et al. (US Pat. 6,492,396, as previously cited).

Regarding **claims 1, 4, 7-8, and 20-23**, Bacon teaches the treatment of multiple sclerosis, Parkinson's disease, and Alzheimer's disease using an effective amount of modafinil in combination with various agents including apomorphine and amphetamine (e.g. Col. 1, line 30-Col. 2, line 12). Multiple sclerosis affects cognitive and/or motor function.

Claims 1, 4, 7, 14-15, and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller et al. (USPGPUB 2001/0034373).

Regarding **claims 1, 4, 7, 14-15, and 22-23**, Miller teaches the administration of an effective amount of modafinil (e.g. less than 200 mg, which includes the range 50-600 mg/day and a dose of 100 mg/day) in conjunction with other pharmaceutical agents for the treatment of impaired cognition associated various disease states including age, trauma, Alzheimer's (which is a degenerative disease), vascular dementia, and schizophrenia, which are a neurostimuli designed to enhance or restore impaired neurological function (e.g. Page 2, Paragraph 14 and 18).

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6, and 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller or Bacon in view of Rise et al. (US Pat. 6,227,203, as previously cited).

Regarding **claims 6**, Miller or Bacon disclose the claimed invention except the use of deep brain stimulation as a neurorehabilitation program. Rise teaches that it was known in the art to administer deep brain stimulation in combination with drug therapy in order to treat an impaired neurological function of an individual who has sustained a brain injury such as those related with Parkinson's disease (e.g. Abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace pharmaceutical neurorehabilitation program of Miller or Bacon with the deep brain stimulation of Rise, since such a modification would provide the system with another alternate way to treat the impaired neurological function for providing the predictable results of improved treatment of impaired neurological function.

Regarding **claims 9 and 10**, Rise additionally discloses that stimulation might be applied periodically during the period of drug infusion or in response to a patient generated demand (e.g. Figure 24; Col. 16, lines 5-20), but does not expressly teach the use of modafinil, as taught by Miller or Bacon. This patient generated demand is an exercise or task to promote or restore an impaired neurological function, and thus the drug modafinil would be administered to an individual prior to or concurrently with the individual performing an exercise or task and stopped after the individual performs an exercise or task and wherein the administration is not resumed until further exercise or task is performed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the drug delivery timing of Rise in the method including the administration of modafinil of Miller or Bacon, since such a modification would provide the system with the predictable results of more accurate therapy.

Regarding **claims 11-12**, neither Miller, Bacon, nor Rise expressly teach a period or rest from the administration of modafinil and, after the period of rest, resuming the therapy with a different does and/or a different neurorehabilitation program that those employed initially. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method taught by Miller or Bacon and Rise in a period or rest and resuming therapy with a different neurorehabilitation program since it was known in the art that adjustment of any therapy program is commonplace and is used to provide the predictable results of improved treatment of impaired neurological function.

Regarding **claim 13**, Miller or Bacon and Rise disclose the claimed invention but do not expressly disclose a resting period of 4 to 12 weeks. It would have been an obvious matter of choice to a person of ordinary skill in the art to modify the method of treating a neurological

disorder with a resting period of 4 to 12 weeks, because Applicant has not disclosed that a resting period of 4 to 12 weeks provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with any period of rest as taught by Miller or Bacon and Rise, because it provides a period of recovery and since it is an arbitrary choice of a rest period length.

Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller or Bacon in view of Ayal et al. (US Pat. 5,892,098).

Regarding **claim 3**, Miller or Bacon disclose the claimed invention except for a neurorehabilitation program that provides physical, occupational, and/or speech therapy. Ayal discloses that it is known in the art to use physical and occupational therapy to treat impaired neurological function, such as those caused by cerebral palsy caused by brain injury (e.g Col. 1, line 48 - Col. 2, line 67). It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the pharmaceutical neurorehabilitation program of Miller or Bacon with any of the treatments of physical and occupational therapy as taught by Ayal, since such a modification would provide the system with another alternate way to treat the impaired neurological function for providing the predictable results of improved treatment of impaired neurological function.

Regarding **claims 4-5**, Miller or Bacon and Ayal disclose the claimed invention except for the a physical/sensory protocol comprising a neurostimulus selected from the group consisting of an exercise or task for motor function, an exercise or task for cognitive function, an exercise or task for a combination of motor and cognitive function, a light stimulation, an audio

stimulation, a visual stimulation, a tactile stimulation, and combinations thereof. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the physical therapy of Ayal with an exercise or task for motor function since it is known in the art that an exercise or task for motor function is used in physical therapy to provided the predictable result of improved treatment of impaired neurological function.

Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bacon in view of "Modafinil: A gift to portmanteau" (by Joshua Cox and Marco Pappagallo, American Journal of Hospice & Palliative Care, Volume 18, Number 6, November/December 2001, hereinafter "Cox").

Regarding **claims 14-16**, Bacon discloses the claimed invention except for the use of an effective dose of 200 mg/day of modafinil. Cox teaches that it was known in the art at the time the invention was made to use a dose of 200 mg/day as an effective amount of modafinil as an adjunct therapy to treat illnesses such as Alzheimer's disease, and multiple sclerosis, which impair neurological function (e.g. Page 409, all Columns). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the effective dose of modafinil of Cox in the method of Bacon, since such a modification would provide the system with a useful dose of modafinil for providing the predictable results of improved treatment of impaired neurological function.

Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller.

Regarding **claim 24**, Miller discloses the claimed invention except for a traumatic brain injury that is the result of a fall on a hard surface, a vehicular accident, or a strike on the head. Miller does disclose, however, providing treatment for non-Alzheimer's dementias, which can be caused as the result of a fall on a hard surface, a vehicular accident, or a strike on the head. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method as taught by Miller with the ability to treat traumatic brain injury that is a result of a fall on a hard surface, a vehicular accident, or a strike on the head, since it is known in the art that non-Alzheimer's dementia can be caused by a fall on a hard surface, a vehicular accident, or a strike on the head.

Regarding **claim 25**, Miller discloses the claimed invention except the express mention that the vascular ischemic event is a stroke. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the vascular ischemic as a stroke since it is well known in the art that a vascular ischemic event can be a stroke.

### ***Response to Arguments***

Applicant's arguments filed January 7, 2008 have been fully considered but they are not persuasive. Regarding Applicant's assertion that Bacon does not teach the limitations of amended claim 1, Examiner disagrees. While the invention as described by Bacon is to that of substituted thioacetamide, the Background of Invention of Bacon describes the use of modafinil (and not a derivative) for the same purposes as those presently claimed.

Applicant's arguments with respect to claims 3, 5-6, 9-16 and 24-25 have been considered but are moot in view of the new ground(s) of rejection. The only reason for the new rejection of

independent claim 1 is that the dependent claims present new combinations of elements not originally presented.

## *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Patton whose telephone number is (571) 270-1912. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AKP/
Examiner, Art Unit 3762

/George R Evanisko/
Primary Examiner, Art Unit 3762